

We claim:

1. Crystalline alfuzosin base.
2. Crystalline alfuzosin base of claim 1, wherein the purity is above 95%.
3. Crystalline alfuzosin base of claim 2, wherein the purity is above 99%.
- 5 4. A process for the preparation of crystalline alfuzosin base of claim 1, which comprises stirring a suspension of impure or noncrystalline alfuzosin base in a ketonic solvent or an alcoholic solvent or mixture thereof.
5. The process according to claim 4, further comprises the crystalline alfuzosin base obtained is collected by filtration or centrifugation.
- 10 6. The process according to claim 4, wherein the ketonic solvent is selected from acetone, methyl ethyl ketone, methyl isobutyl ketone, methyl isopropyl ketone and methyl tert-butyl ketone; and alcoholic solvent is selected from methanol, ethanol, isopropyl alcohol and tert-butyl alcohol.
7. The process according to claim 6, wherein the ketonic solvent is acetone or
15 methyl isobutyl ketone.
8. The process according to claim 7, wherein the ketonic solvent is acetone.
9. The process according to claim 7, wherein the ketonic solvent is methyl isobutyl ketone.
10. The process according to claim 6, wherein the alcoholic solvent is methanol
20 or ethanol.
11. The process according to claim 10, wherein the alcoholic solvent is methanol.
12. The process according to claim 4, wherein the suspension is stirred for at least 30 minutes at below boiling temperature of the solvent used.
- 25 13. The process according to claim 12, wherein the suspension is stirred for 1 hour to 4 hours at 25 - 60°C.
14. A process for the preparation of crystalline solid of alfuzosin base, which comprises dissolving alfuzosin base in a ketonic solvent or an alcoholic solvent or mixture thereof and crystallizing alfuzosin base from the solution.
- 30 15. The process according to claim 14, further comprises the crystalline alfuzosin base is collected by filtration or centrifugation.
16. The process according to claim 14, wherein the crystallization is initiated by a method such as cooling, seeding, partial removal of the solvent from the solution, by adding an anti-solvent to the solution or a combination thereof.

17. The process according to claim 14, wherein the ketonic solvent is selected from acetone, methyl ethyl ketone, methyl isobutyl ketone, methyl isopropyl ketone and methyl tert-butyl ketone; and alcoholic solvent is selected from methanol, ethanol, isopropyl alcohol and tert-butyl alcohol.
- 5 18. The process according to claim 17, wherein the ketonic solvent is acetone or methyl isobutyl ketone.
19. The process according to claim 18, wherein the ketonic solvent is acetone.
20. The process according to claim 18, wherein the ketonic solvent is methyl isobutyl ketone.
- 10 21. The process according to claim 17, wherein the alcoholic solvent is methanol or ethanol.
22. The process according to claim 21, wherein the alcoholic solvent is methanol.
- 15 23. A process for the preparation of crystalline solid of alfuzosin base, which comprises treating an acid addition salt of alfuzosin with a base to liberate alfuzosin base, isolating by forcible or spontaneous crystallization from a ketonic or an alcoholic solvent or mixture thereof.
24. The process according to claim 23, further comprises the crystalline alfuzosin base is collected by filtration or centrifugation.
- 20 25. The process according to claim 23, wherein forcible crystallization is initiated by a method such as cooling, seeding, partial removal of the solvent from the solution, by adding an anti-solvent to the solution or a combination thereof.
- 25 26. The process according to claim 23, wherein the ketonic solvent is selected from acetone, methyl ethyl ketone, methyl isobutyl ketone, methyl isopropyl ketone and methyl tert-butyl ketone; and alcoholic solvent is selected from methanol, ethanol, isopropyl alcohol and tert-butyl alcohol.
27. The process according to claim 26, wherein the ketonic solvent is acetone or methyl isobutyl ketone.
- 30 28. The process according to claim 27, wherein the ketonic solvent is acetone.
29. The process according to claim 27, wherein the ketonic solvent is methyl isobutyl ketone.
30. The process according to claim 26, wherein the alcoholic solvent is methanol or ethanol.

31. The process according to claim 30, wherein the alcoholic solvent is methanol.
32. The process according to claims 4, 14 and 23, which further comprises crystalline alfuzosin base is converted into a pharmaceutically acceptable salt of alfuzosin.
33. The process according to claim 32, wherein the pharmaceutically acceptable salt of alfuzosin is alfuzosin hydrochloride.
34. A process for the preparation of alfuzosin base or a pharmaceutically acceptable salt thereof, which comprises reacting N₁-(4-Amino-6,7-dimethoxyquinazol-2-yl)-N₁-methylpropylenediamine with activated tetrahydro-2-furoic acid by adding the said activated tetrahydro-2-furoic acid to the said diamine compound, isolating impure alfuzosin base from the reaction mixture, converting the said base into crystalline solid, optionally converting the said crystalline solid into pharmaceutically acceptable salt of alfuzosin.
35. The process according to claim 34, wherein the pharmaceutically acceptable salt is alfuzosin hydrochloride.
36. The process according to claims 34 and 35, wherein the impure alfuzosin base is converted into the said crystalline alfuzosin base by suspending the impure alfuzosin in a ketonic or an alcoholic solvent, stirring for at least 30 minutes at about 25 - 60°C, filtering or centrifuging, dissolving the obtained solid in an alcoholic or ketonic solvent, crystallizing and filtering to form crystalline alfuzosin base.
37. The process according to claim 36, wherein the solvent used for suspension is acetone.
38. The process according to claim 36, wherein the solvent used for dissolving alfuzosin base is methanol.
39. The process according to claims 34 and 35, wherein the impure alfuzosin is converted into crystalline solid by isolating as an acid addition salt, treating the salt with a base to liberate alfuzosin base, crystallizing from a ketonic or alcoholic solvent.
40. The process according to claim 39, wherein the acid addition salt is hydrochloride salt of alfuzosin, the solvent used for crystallization is methanol or acetone.

41. The process according to claims 34 and 35, wherein impure alfuzosin base is converted into the said crystalline alfuzosin by dissolving impure alfuzosin in a ketonic or an alcoholic solvent or a mixture thereof and crystallizing alfuzosin base from the solution.
- 5 42. The process according to claim 41, wherein the ketonic solvent is acetone or methyl isobutyl ketone and the alcoholic solvent is methanol or ethanol.
43. The process according to claims 34 and 35, wherein impure alfuzosin base is converted into the said crystalline alfuzosin by converting alfuzosin base into an acid addition salt thereof, isolating the salt obtained from the reaction mixture, reacting the salt with a base to liberate alfuzosin base, isolating alfuzosin base obtained from the reaction mixture, dissolving alfuzosin base in a ketonic solvent or an alcoholic solvent or mixture thereof and crystallizing alfuzosin base from the solution.
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44. The process according to claim 43, wherein the acid addition salt is hydrochloride salt, the base is selected from hydroxides, carbonates or bicarbonates of sodium and potassium, the ketonic solvent is acetone or methyl isobutyl ketone and alcoholic solvent is methanol or ethanol.
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45. The process according to claims 34 and 35, wherein impure alfuzosin base is converted into the said crystalline alfuzosin by converting alfuzosin base into an acid addition salt thereof, isolating the salt obtained from the reaction mixture, reacting the salt with a base to liberate alfuzosin base, isolating alfuzosin base obtained from the reaction mixture, suspending alfuzosin base in a ketonic solvent or an alcoholic solvent or mixture thereof for 1 hour to 4 hours at 25 - 60°C and collecting crystalline alfuzosin base by filtration or centrifugation.
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46. The process according to claim 45, wherein the acid addition salt is hydrochloride salt, the base is selected from hydroxides, carbonates or bicarbonates of sodium and potassium, the ketonic solvent is acetone or methyl isobutyl ketone and alcoholic solvent is methanol or ethanol.